Society Joins Call for Review of Incretin-based Therapy for Diabetes Mellitus
June 18, 2013

A range of data exists to support or refute the association of GLP-1 receptor agonists and DPP-4 inhibitors with pancreatic disease. These data have limitations based on varying methodology and outcomes and are not the types of studies that have typically been used to validate adverse events. The Endocrine Society believes that more research is needed in all areas of incretin-based therapy before any conclusion can be reached about its safety with regard to pancreatitis and pancreatic cancer risk.

Important safety data will result from the Safety Evaluation of Adverse Reactions in Diabetes (SAFEGUARD) program which was established by the European Medicines Agency and funded by the European Union (EU). It will combine data from nine population-based health care databases in six countries in the EU and the United States, capturing drug exposure from 1999-2012 and event data on >35 million patients (1.7 million with type 2 diabetes). This is compatible with >240 million patient-years. It also will include an intervention arm with appropriate biochemical and imaging studies. In addition, individual level data will become available over the next few years as a result of the ongoing large cardiovascular safety trial of DPP-4 inhibitors alogliptin (EXAMINE), linagliptin (CAROLINA), saxagliptin (SAVOR-TIMI53), and sitagliptin (TECOS) and GLP-1 receptor agonists duraglutide (REWIND), exenatide (EXSCEL), liraglutide (LEADER), and lixisenatide (ELIXA).

We urge all manufacturers of incretin-based therapy to make the data from these studies on rates of pancreatitis and pancreatic cancer transparent and available to an independent group of scientists for analysis as it becomes available. We support the American Diabetes Association’s offer to coordinate that effort.

In the meantime, we reiterate our recommendations to diabetes care providers and patients contained in our Statement of March 1, 2013:

Patients should be made aware of this potential side effect of incretin-based therapy and the symptoms of pancreatitis.

Diabetes care providers should consider the possible adverse effects as they balance risk and benefit of particular treatment paradigms, especially in patients with other risk factors for pancreatitis.

We discourage patients from stopping medications on their own without consulting their health care provider, since this can lead to higher levels of blood glucose that may cause serious short-term health problems and, if prolonged, could increase the risk of long term diabetes-related complications.